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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,331	10/07/2003	Takashi Tokuyama	F-7995	5419

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EXAMINER

WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1655

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,331

Applicant(s)

TOKUYAMA ET AL.

Examiner

Randall Winston

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-53 is/are pending in the application.
- 4a) Of the above claim(s) 48-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 0804.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 23-47 and its election of species of a) ethanolamine b) 1,3-butyleneglycol c) antiphlogistic agent in its response to the restriction requirement of 02/02/2006 is acknowledged. The traversal is based on the grounds that Office Action does not indicate any claims directed to fewer than the species under Species Group A, Species Group B or Species Group C. Furthermore, the Office Action does not indicate and explain that the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search would be necessary to search the entire scope of the claim. Thus, since only generic claims are presented regarding Species Groups A, B, and C, restriction of species can not be required at this time pursuant to MPEP 808.01(a).

Applicant's argument is not found persuasive because Applicant did not submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case.

Moreover, the search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all the above inventions in one application.

The restriction requirement is still deemed proper and is therefore made final.

Claims 48-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Readable claims 23-47 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a skin conditioner composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent, the specification does not enable any person skilled in the art to prepare a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 6-56, examples 1-15, of the specification a skin conditioner composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent.

Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a composition for prevention of exacerbation and/or prevention of any disease comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-38 and 41-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Yoshioka et al. (US 5,753,214) as evidenced by Pearson et al. (6,951,658).

Applicant claims a skin conditioner composition comprising L-arginine, ethanolamine and an antiphlogistic agent (i.e. an anti-inflammatory agent).

Yoshioka anticipates (see, e.g. column 8 lines 54-67, column 9 lines 1-35, column 17 lines 23-34) the claimed invention because Yoshioka teaches a skin conditioner composition comprising L-arginine (please note, as evidenced by Pearson et al. L-arginine is inherently found in rice, thus, it is considered a "rice preparation"), ethanolamine and an antiphlogistic agent (i.e. anti-inflammatory agent).

Therefore, the reference is deemed to anticipate the claimed invention.

Please note, the intended use of the above claimed composition (i.e. the claimed treatment for atopic dermatitis and other claimed diseases of claims 43-47) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Please note that the patentability of a product (i.e. L-arginine originated in a rice preparation and/or plant preparation) does not depend upon the method of production. If

the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshioka et al. (US 5,753,214) in view of Ikemoto et al. (US 6,497,898) as evidenced by Pearson et al. (6,951,658)

Applicant claims a skin conditioner composition comprising L-arginine, ethanolamine, 1,3-butyleneglycol and an antiphlogistic agent (i.e. anti-inflammatory agent).

The primary reference is relied upon for the reasons discussed above. Yoshioka et al. do not expressly teach a moisture retention agent of 1,3-butyleneglycol included within its claimed composition.

Ikemoto et al. teaches (see, e.g. column 4 lines 44-53) 1,3-butyleneglycol contained within a skin conditioner composition (i.e. cosmetic).

One of ordinary skill in the art of creating the claimed invention skin conditioner composition would have been motivated to modify Yoshioka's skin conditioner composition to include the active ingredient taught in Ikemoto because the above combined two references teachings as a whole would create an improved skin conditioner composition.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
2-28-06
SUSAN COE
PRIMARY EXAMINER